

## **REMARKS/ARGUMENTS**

These amendments and remarks are being filed in response to the final Office Action mailed August 8, 2007. Please be advised that a Request for Continued Examination, along with the required fee, was filed in this matter on October 31, 2007.

In the final Office Action, Claims 22, 25-41, and 43 were rejected under 35 U.S.C. § 102(b) as being anticipated by Brix (US 1,513,367).

A brief review of Applicant's invention may be helpful prior to discussing the relevant references. Applicant's invention is directed to an obesity device that is positioned adjacent to the trachea side of the upper quadrant of a human stomach, with a front side member and a backside member forming a substantially continuous clamping of the stomach so as to form a canal within the stomach that is an extension of the esophageal canal to limit the rate of flow of ingested material into the stomach and to limit the digestion and absorption of the ingested material. The device remains in place around the stomach post-operatively. The invention relies on the external clamping effect and does not have piercing projections and avoids the severe and irreversible damage to the stomach that results from prior surgical procedures such as vertical banded gastroplasty. The external clamping of the stomach, however, creates some specific challenges. The stomach is bound by tissues to surrounding body structures, and the abdominal cavity is in general a very closed-in space. The positioning and securing of such an external clamp is accordingly difficult.

Applicant's invention addresses the afore-mentioned problems by providing a device in which a front side member is detachably engaged to a connector and, through the connector, to the backside member. The device has a substantially u-shaped cross section to permit placement over the stomach and the desired clamping effect. The front side member in one configuration is

completely detached from at least one of the connector and the backside member. The backside member can be placed into position without the front side member in the way. This minimizes the disruption to surrounding tissues. The connector has a receiving portion that is angularly moveable and detachably engages the front side member. The front side member can thereby be easily positioned and attached after the backside member is placed into position behind the stomach. Further, the receiving portion of the connector is angularly movable, which permits the ready attachment of the front side member to the connector from a number of different angles, thereby further facilitating the installation process. Also, the connector has a clamp adjusting mechanism for adjusting the distance between the front side member from the backside member. This allows the positioning of the device while in a wide or "loose" configuration, and then adjustment of the clamping mechanism to clamp the stomach to the degree desired. The adjustable clamping structure further permits the device to be readily removed, or to have the clamping strength adjusted after installation. Together with the angularly moveable receiving portion and the completely detachable front side member, the invention provides a degree of versatility and adjustability heretofore unavailable in stomach stricture devices.

Brix (US 1,513,367) describes a stomach clamp having a planar front side member (17) and backside member (17a), a connector (10), a clamp adjusting mechanism (15 and 15a), an angularly moveable receiving portion (18); a positioning member (12); a connector slot (21); anchoring slots (22); corresponding engagement structure (the slots can engage 13 and 13a on the positioning member); and front and backside apertures (19 and 19a).

Brix does not disclose the present invention, nor provide the features or advantages of the present invention. Brix discloses a variation on a typical clamp useful in various types of surgery. Brix is a variation in that it provides a double-clamp construction rather than the more

typical single clamp. However, neither Brix nor other surgical clamps disclose the invention. These are devices that are used during surgery to retain organs or tissue in a desired position. The construction of these devices is such that they could not be left in the patient post-operatively. Indeed, to do so would risk trauma to the patient. Brix does not have a front side member that is completely detachable from at least one of the connector and the back side member. Brix therefore could not be placed around the patient's stomach in a manner suitable for post-operative stomach stricture.

The backside member must first be carefully positioned behind the stomach. Only then can the front side member be connected to the backside member. If this were not the case, the dimensions of an integral clamp such as shown by Brix would not permit proper positioning of the backside member behind the stomach suitable for stomach stricture. The jaws 17 and 17a of Brix, which would form the front side member and the backside member if an attempt were made to use the Brix device for post-operative stomach stricture, move in parallel orientation, and are not angularly moveable relative to each other in a manner made possible by Applicant's angularly moveable receiving portion. Applicant can find no portion of the jaws 17 and 17a that are completely detachable from the rest of the device.

The present invention is designed to be placed onto the stomach and left in place post-operatively. The device has a substantially u-shaped cross section to permit placement over the stomach and the desired clamping effect. Brix is not u-shaped but rather x-shaped, and the grip 11 and handles 15 of Brix render this construction unusable for proper positioning of the backside member in the tight spaces of the abdomen as is necessary for post-operative stomach stricture.

Applicant requests reconsideration and allowance of the pending claims. This Response is accompanied by a Petition for Retroactive Extension of Time, along with authorization to charge the fee for a three month extension of time, as well as any underpayment in fees, to Deposit Account No. 50-0951.

Respectfully submitted,

AKERMAN SENTERFITT

A handwritten signature in black ink, appearing to read 'Gregory A. Nelson', is written over a horizontal line.

Dated: February 7, 2008

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